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| FORM PTO-1449 (REV. 7-80) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO.: 653.1003 | | SERIAL NO.: 09/872,430 | |
| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | | | RECEIVED AUG 29 2002 | | 1631 TECH CENTER 1600/2900 | |
| | | | | APPLICANT(S): Donald P. REITBERG | | | |
| <div style="border: 1px solid black; border-radius: 50%; padding: 10px; display: inline-block;"> OIPE AUG 26 2002 U.S. DEPT. OF COMMERCE PATENT & TRADEMARK OFFICE </div> | | | | FILING DATE: June 1, 2001 | | GROUP: 1631 | |
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| U.S. PATENT DOCUMENTS | | | | | | | |
| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| OPL | AA 6 0 2 9 1 3 8 | 02/22/00 | Khorasani et al. | 705 | 2 | 08/15/97 | |
| | AB 5 9 9 1 7 3 1 | 11/23/99 | Colon et al. | 705 | 3 | 02/01/99 | |
| | AC 5 5 9 4 6 3 7 | 01/14/97 | Eisenberg et al. | 395 | 202 | 05/26/93 | |
| | AD | | | | | | |
| | AE | | | | | | |
| | AF | | | | | | |
| | AG | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
| | | | | | | YES | NO |
| OPL | AH 9 8 1 2 6 6 9 | 03/26/98 | WO | | | | |
| | AI 1 0 2 1 4 2 9 | 06/11/98 | Japan | | | | X |
| | AJ | | | | | | |
| | AK | | | | | | |
| | AL | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | |
| OPL | AM | WEINHOLD, L.L. et al., "A Meta-analytic Model for Integrating Outcomes in Drug Research: Subjective Effects of Phenylpropanolamine Related to Abuse Potential," Journal of Clinical Research and Drug Development. 1994 Vol.8, pages 57-71. | | | | | |
| | AN | SACHIDANANDAM, R. et al., "A map of human genome sequence variation containing 1.42 million single nucleotide polymorphisms," Nature. 15 February 2001, Vol. 409, pages 928-933. | | | | | |
| | AO | LARSON, E.B. et al., "Randomized Clinical trials in Single Patients During a 2-Year Period," Journal of the American Medical Association. 08 December 1993, Vol. 270, No. 22, pages 2708-2712. | | | | | |
| | AP | EVANS, W.E. et al., "Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics," Science. 15 October 1999, Vol. 286, pages 487-491. | | | | | |
| | AQ | Abstract of JP 1021429 (English) | | | | | |
| | AR | | | | | | |
| EXAMINER | | | | DATE CONSIDERED | | | |
| | | | | 1/28/04 | | | |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | |

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
853.1003SERIAL NO.:
09/872,430

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APPLICANT(S): REITBERG, Donald P.

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
|------------------|----------|---------|-------|----------|-------------|
| AB 0 4 5 9 3 8 7 | 04/12/91 | Europe | G01N | 33/533 | English |

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|----|--|
| AC | Sheather-Reid, R. et al., "Efficacy of Analgesics in Chronic Pain: A Series of N-of-1 Studies", <u>Journal of Pain and Symptom Management</u> , Vol. 15, No.4, 1988; pgs. 244-252. |
| AD | Jaeschke, R. et al., "Clinical Usefulness of Amitriptyline in Fibromyalgia: Results of 23 N-of-1 Randomized Controlled Trials", <u>The Journal of Rheumatology</u> , Vol. 18, No. 3, 1991; pgs. 447-451. |
| AE | Patel, A. et al., "Clinical Usefulness of n-of-1 Randomized Controlled Trials in Patients with Nonreversible Chronic Airflow Limitation", <u>AM REV RESPIR DIS</u> , 1991; 144:962-964. |
| AF | Balestra, D. et al., "Ulcerative Colitis and Steroid-Responsive, Diffuse Interstitial Lung Disease", <u>JAMA</u> , July 1, 1988; Vol. 260 No. 1 |
| AG | Max, M.B. et al., "The Design of Analgesic Clinical Trials", <u>Advances in Pain Research and Therapy</u> , Vol. 18, 1991; 178-192. |
| AH | Cook, D. et al., "A Diagnostic and Therapeutic N-of-1 Randomized Trial", <u>Canadian Journal of Psychiatry</u> , Vol. 38, 1993; 251-254. |
| AI | Guyatt, G.H. et al., "A clinician's guide for conducting randomized trials in individual patients", <u>CMAJ</u> , Vol. 139, 1988; 497-503. |
| AJ | Wulff, H.R., "Single Case Studies An Introduction", <u>Scandinavian Journ. of Gastroenterology</u> , 1988, Vol 23. S. 147, pgs. 7-10. |
| AK | Keller, J. et al., "An N of 1 Service: Applying the Scientific Method in Clinical Practice", <u>Scandinavian Journ. of Gastroenterology</u> , 1988, Vol 23. S. 147, pgs. 22-29. |
| AL | Guyatt, G.H. et al., "N-of-1 Randomized Trials for Investigating New Drugs", <u>Controlled Clinical Trials</u> , 11:88-100 (1990). |
| AM | Larson, E.B., "N-of-1 Clinical Trials A Technique for Improving Medical Therapeutics", <u>The WESTERN JOURNAL OF MEDICINE</u> , 1990; 52-56. |
| AN | Biosis 94:537363 (1994) |
| AO | Guyatt <i>et al.</i> (1990) N-of-1 Randomized Trials-Where Do We Stand? <u>Western Journ. of Med.</u> , 152(1): 67-8. |
| AP | Johannsen <i>et al.</i> (1991) Combined Single Subject Trials. <u>Scandinavian Journ. of Primary Health Care</u> , 8(1): 23-7. |
| AQ | Johannsen <i>et al.</i> (1992) Cimetidine On Demand In Dyspepsia. <u>Scandinavian Journ. of Gastroenterology</u> , 27(3): 189-95 |
| AR | Spitzer, Bert, "Planning Special Types of Clinical Trials: Single-Patient Clinical Trials" <u>Guide to Clinical Trials</u> , Part III, Chapter 38 pgs 277-282. 1996 |

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FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
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LIST OF PRIOR ART CITED BY APPLICANT

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APPLICANT(S): REITBERG, Donald P.

FILING DATE: June 1, 2001

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U.S. PATENT DOCUMENTS

| *EXAMINED INITIALS | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
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FOREIGN PATENT DOCUMENTS

| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
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| BB | | | | | |

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, Etc.)

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|------|----|--|
| col. | BC | Langer, C. et al., "The Single Subject Randomized Trial A Useful Clinical Tool for Assessing Therapeutic Efficacy in Pediatric Practice", <u>Clinical Pediatrics</u> , Nov. 1993; 654-657. |
| | BD | Guyatt, G.H., et al., "The n-of-1 Randomized Controlled Trial: Clinical Usefulness", <u>Annals of Internal Medicine</u> , 1990; 112:293-298. |
| | BE | Spiegelhalter, D., "Statistical Issues in Studies of Individual Response", <u>Scandinavian Journ. of Gastroenterology</u> , 1988, Vol 23. S. 147, 40-45. |
| | BF | Larson, E.B. et al., "Randomized Clinical Trials in Single Patients During a 2-Year Period", <u>JAMA</u> , Vol. 270, No. 22, 1993; 2708-2712. |
| | BG | Robin, E. et al., "Single Patient Randomized Clinical Trial Opiates for Intractable Dyspnea", <u>CHEST</u> , 1988; 90:888-892. |
| | BH | Gibaldi, M., et al., "Single-Patient Drug Trials", <u>Perspectives in Clinical Pharmacology</u> , Vol. 4, No. 11, 1986, pages 81-83 |
| | BI | Guyatt, G., et al., "Determining Optimal Therapy-Randomized Trials in Individual Patients", <u>The New England Journal of Medicine</u> , Vol. 14, No. 14, 1986, pages 889 - 892 |
| | BJ | McLeod, R.S., et al., "Single-Patient Randomised Clinical Trial", <u>The Lancet</u> , 1986, pages 726-728 |
| | BK | Larson, E.B., et al., "Randomized Clinical Trials in Single Patients During a 2-Year Period", <u>JAMA</u> , Vol. 270, No. 22, pages 2708-2710 |
| | BL | Anonymous, May 31, 1986, "Single-Patient Trials" Editorial Section, <u>The Lancet</u> |
| | BM | Zucker, D.R., et al., "Combining Single Patient (N-of-1) Trials to Estimate Population Treatment Effects and to Evaluate Individual Patient Responses to Treatment", <u>Journal of Clinical Epidemiology</u> , Vol. 50, No. 4, 1997; pp. 401-10. |
| | BN | |
| | BO | |
| | BP | |
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